INFORMATION FOR APPLICANTS PREPARING A SUBMISSION FOR THE 2023 MEETING OF THE WHO EXPERT COMMITTEE ON SELECTION AND USE OF ESSENTIAL MEDICINES

Essential Medicines List Secretariat

DEPARTMENT OF HEALTH PRODUCTS POLICY AND STANDARDS

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Preface

The 24th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines to revise and update the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc), will take place in April 2023.

This document describes the requirements for information to be included in submissions for inclusion of new medicines, for inclusion of new indications of currently listed medicines, and deletion of currently listed medicines for consideration by the Expert Committee.

For submissions relating to the inclusion or deletion of individual dosage form(s) and/or strength(s) of currently listed medicines for existing indications, please contact the EML Secretariat for further information.

During the submission period, the EML Secretariat is available to provide information and support to applicants, to ensure submissions adequately address the submission requirements. Final submissions must be emailed to the EML Secretariat (emlsecretariat@who.int) in both PDF and Word formats by 16 December 2022, 18:00 UTC.

Please direct all enquiries to:

The Secretary
WHO Expert Committee on Selection and Use of Essential Medicines
Essential Medicines Team
Department of Health Products Policy and Standards
World Health Organization, Geneva
emlsecretariat@who.int

- All submissions accepted for consideration by the Expert Committee will be published on the WHO website and should not include information that is commercial in confidence.

Contents

Information to be included in submissions for inclusion or deletion of a medicine in the WHO Model Lists of Essential Medicines

1. TITLE PAGE

All submissions must have a title page describing the purpose of the submission and include the name and contact information of the individual(s) and/or organization(s) responsible.

2. SUMMARY STATEMENT OF THE PROPOSAL FOR INCLUSION, CHANGE OR DELETION

For **inclusions** of new medicines or new indications for currently listed medicines, briefly describe the proposal in terms of clinical indication(s), target population(s) and role in therapy for the requested medicine(s).

For **deletion** of medicines or indications, briefly describe the rationale and justification for the proposed deletion.

In all cases, specify whether the proposal relates to listing on the EML and/or EMLc, the core or complementary list, and of an individual medicine or as a representative of a pharmacological class or therapeutic group ("square box listing" – in which case the therapeutic alternatives should also be specified). For an explanation of the different terms, see below.

- The Essential Medicines List for Children (EMLc) is intended for use for children up to and including 12 years of age.
- The core list presents a list of minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.
- The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt, medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings.
- A "square box" symbol (☐) is intended to indicate therapeutic alternatives to the listed medicine that may be considered for selection in national essential medicines lists. Alternatives may be individual medicines, or multiple medicines within a pharmacological class or chemical subgroup, defined at the 4th level of the Anatomical Therapeutic Chemical (ATC) classification, which have similar clinical effectiveness and safety. The listed medicine should be the example of the class or subgroup for which there is the best evidence for effectiveness and safety. A square box is not used to indicate alternative generic brands of the same small molecule medicines, nor alternative biosimilars of biological medicines.

Summary statement examples (illustrative purpose only):

This submission advocates the inclusion of daratumumab as an individual medicine in the complementary list of the EML for the treatment of adult patients with newly diagnosed and relapsed or refractory multiple myeloma in transplant and non-transplant settings.

Results of the evidence syntheses indicate that adding daratumumab to standard combination regimens probably leads to clinically important gain of overall survival, yet a higher number of people experiencing adverse events or serious adverse events. Evidence further suggests that more people receiving daratumumab may have a clinically important gain of quality of life, than people no receiving daratumumab.

Multiple myeloma is the second most common haematological malignancy with a global incidence of approximately 140,000 and an age-standardized incidence rate of 2.1 per 100,000 population in 2016. Since 1990, the incidence rate increased by 126% worldwide.

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This submission is made in support of the inclusion of calcipotriol on the core list of the EML and EMLc, for the treatment of plaque type psoriasis in adults and children. This proposal is being made because there are currently no topical alternatives to the use of topical corticosteroids for the treatment of psoriasis included on the Model Lists. Listing is proposed for calcipotriol as the representative of topical vitamin D analogues, with therapeutic alternatives limited to calcitriol and tacalcitol.

Psoriasis is increasingly recognized as a disabling skin disease and has a worldwide distribution. Effective treatment of patients with mild to moderate plaque type psoriasis with calcipotriol has been reported in different clinical environments and in different age groups. Inclusion of calcipotriol on the Model Lists for the proposed indication would widen access to appropriate medications for the treatment of psoriasis and provide an effective alternative for the many patients with mild to moderate forms of this chronic condition who comprise the majority of cases.

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This submission proposes the deletion of saquinavir (solid oral dosage form, 200 mg) from the core list of